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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,083	10/22/2003	William Martin Belef	704117.4005	8282

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EXAMINER	
GANESAN, SUBA	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,083	BELEF ET AL.	
	Examiner	Art Unit	
	Suba Ganesan	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/22/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/22/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/6/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 5 is objected to because of the following informalities: the abbreviation "RF" should be changed to ---radio frequency--- for clarity. Appropriate correction is required.

2. Claim 15 is objected to because of the following informalities: the use of the word "final" appears to be a typo of the word ---spinal---. Appropriate correction is required.

3. Claim 32 is objected to because of the following informalities: the abbreviation "nsaid" should be changed to ---non-steroidal anti-inflammatory drug--- for clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims **1-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Lambrecht et al. (U.S. Pat. No. 6,482,235).

Lambrecht et al. discloses a method for augmenting an intervertebral disc in order to repair defects in the annulus fibrosis including creating an opening through the annulus fibrosis into the interior of the disc (see figure **19**). Regarding claims 1-4, Lambrecht discloses removing a portion of the nucleus pulposus (col. 17 lines 4-7),

introducing an implanted barrier (**12**). The barrier (**12**) is considered to be a therapeutic agent.

Lambrecht further discloses using radio frequency energy (col. 20, line 29) by introducing an 'elongate member' (**130**) with electrodes disposed on its distal portion, those electrodes being activated while the elongate member is within the interior of the disc. With respect to claim 6, a distal end of a needle is used to deliver barrier (**12**) (see fig. 29 A-D). A thermal device (**30**) is attached to the elongate member (**130**) that delivers electrical energy to the surrounding tissue in order to close the passage (see fig. 29 D). With respect to claim 12, Lambrecht discloses a secondary object (**418**) that is a handle member that has an electrically conductive filament (col. 27 lines 38-44).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims **13** and **14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht '235 in view of Underwood et al. (U.S. Pat. No. 6,929,640).

Lambrecht is explained as above. However, Lambrecht does not disclose the injection of a therapeutic agent using a syringe, or disconnecting the syringe before connecting a handle member to the needle. Underwood discloses a device for closing openings in the interior of spinal discs using radio frequency energy transmitted via

electrodes on the distal portion of an 'elongate element' (**306**). Underwood further discloses the use of a needle and syringe for the purpose of delivering saline solution to the area (see fig 16). Therefore it would have been obvious to one of ordinary skill in the art to modify Lambrecht with the syringe delivery system of Underwood for the purpose of delivering a therapeutic agent, such as an irrigant.

8. Claims **15-18, 20,23,** and **27-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning (U.S. Pat. No.3,875,595) in view of Lambrecht '235.

Froning discloses a method of treating a spine, including the steps of removing at least portion of the nucleus pulposus from an interior region of a spinal disc to define a space; lining the space with a nonporous liner material or bladder (**46**); and filling the space with a fill material or fluid to expand the liner material (see Figures 1-8). The bladder includes a neck with an opening and a sealing member. However, Froning does not disclose the liner material being bioabsorbable, the use of energy to close the opening in the annulus fibrosis or the fill material used in the method being the nucleus pulposus from the disc.

Lambrecht teaches the use of resorbable materials such as polylactic acid and polyglycolic acid (for example see col. 11 lines 38-41). Lambrecht further teaches the use of radio frequency energy (col. 20 line 29) in order to close an opening in the annulus fibrosis. Therefore it would have been obvious to one of ordinary skill in the art to modify Froning with the radio frequency energy and bioabsorbable materials of Lambrecht in order to close an opening in the annulus fibrosis and to allow the lining to resorb over time.

With respect to claim **16**, Lambrecht teaches the use of the nucleus pulposus within a defect (col. 21 line 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to practice the method of Froning with the fill material or fluid being the nucleus pulposus from the disc, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Moreover, applicant has not disclosed that use of the nucleus pulposus solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well if the fill material did not have any nucleus pulposus from the disc.

Regarding claim **17**, it would have been obvious to one of ordinary skill in the art to use the nucleus pulposus from the same patient in order to avoid homologous reactions. With respect to claim **18** and **28**, it is known that using the nucleus pulposus means that naturally occurring extra-cellular matrix material is used (the natural material surrounding the chondrocyte-like cells of the nucleus pulposus). Furthermore, with respect to claim **20**, nucleus pulposus from the same patient comprises an autologous therapeutic agent.

With regard to the fill material further having at least one of, a concentrated growth factor derived from centrifuged plasma of the patient (claim **21**), it is noted that it would have been further obvious to one having ordinary skill in the art at the time the invention was made to practice the modified method of Froning with the fill material further having a concentrated growth factor derived from centrifuged plasma of the

patient since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

9. Claim **19**, and **24-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning '595 in view of Lambrecht '235 as applied to claim 15 above, and further in view of Carr Jr. et al. (U.S. Pat. No. 5,733,337). Froning in view of Lambrecht discloses same as above. However, Froning in view of Lambrecht does not disclose a fill material comprised of at least one of intestinal submucosa, stomach submucosa, or bladder submucosa. Carr Jr. et al. discloses the use of intestinal submucosa (col. 2-3, lines 66-3) for biodegradable implantation within the body. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Froning in view of Lambrecht to further include the use of intestinal submucosa for the purpose of making the implant biodegradable. It is also noted that intestinal submucosa comprises an extra-cellular matrix material.

10. Claim **22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Froning '595 in view of Lambrecht '235 as applied to claim 15 above, and further in view of Felt et al. (U.S. Pat. No. 6,140,452). Froning in view of Lambrecht discloses same as above. However, Froning in view of Lambrecht does not disclose filler material comprising an interpenetrating polymer network material. Felt et al. teaches the use of an interpenetrating polymer network (for example, see col. 30 lines 36-40) in order to utilize a multiphasic bulk morphology. Therefore it would have been obvious to one of ordinary

skill in the art to modify Froning in view of Lambrecht with the interpenetrating network of Felt et al. in order to have a filler material with multiphasic bulk morphology.

Claims **30-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning in view of Lambrecht '235 as applied to claim 27 above, and further in view of Michelson (U.S. Patent 4,968,298).

Froning, as applied to claim **27**, discloses the claimed invention except for the step of introducing a flowable fill material into the interior region of the disc before introducing the lining. Michelson teaches to irrigate or wash out disc interspace after the material from the disc has been removed, in order to remove any disc fragment and prevent inflammation of the neural elements and/or further surgery (see col. 1 line 5, through col. 2 line 46). It would have been obvious to one skill in the art at the time the invention was made to practice the method of Froning including the step of irrigate or wash out the interior region of the disc in view of Michelson, in order to be sure that no fragments of the nucleus pulposus are left inside the disc thus preventing inflammation and/or further surgery. With regard to claims **31-33**, it would have been further obvious to one having ordinary skill in the art at the time the invention was made to irrigate or wash out the interior of the disc with naturally occurring extra-cellular matrix material, a slurry of at least one of saline, an antibiotic, a steroid, and a non-steroidal anti-inflammatory drug, or an autologous therapeutic agent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cragg et al. disclose a method of introducing therapeutic material in the spine. Ashley et al. teach a method of applying energy to the spine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 5712723243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG
8/27/2006

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

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